



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

**WARNING LETTER NYK 1999-37**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

March 11, 1999

Mr. Stephen Odland  
President/CEO  
TOPS Markets, Inc.  
6363 Main Street  
Williamsville, New York 14221

Dear Mr. Odland:

The Food and Drug Administration (FDA) has information which shows your firm violated the Federal Food, Drug, and Cosmetic Act.

On January 11, 1999, your firm imported assorted pizza products into the United States under Entry No. F57-0864157-9. Since the necessary documentation was not presented at the time of entry, FDA issued a request for documents to the customhouse broker (Willson Freight Services, Tonawanda, New York) on January 15, 1999. These were received by this office on February 22, 1999. Subsequent investigation by this office conducted on February 25, 1999 revealed the entry was not held intact. We were advised the entire lot had been distributed to various TOPS locations in New York and Pennsylvania. We are hereby requesting U.S. Customs to order redelivery of this shipment (copy enclosed).

This action taken by your firm is in violation of 21 CFR 1.90 which requires an importer to hold an entry intact pending receipt of a "May Proceed" or "Release Notice" from the FDA. A "Release" by the U.S. Customs Service is a conditional release which merely permits you to take possession of the shipment. When other Federal Agencies, such as the FDA, also exercise jurisdiction over a product offered for importation, their release must also be obtained before a product may be legally distributed.

Failure to promptly correct these violations and prevent future violations may result in regulatory action without future notice such as seizure or automatic detention to ensure that imported products are held intact until released by the FDA. It is your responsibility, as the owner/importer, to ensure imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

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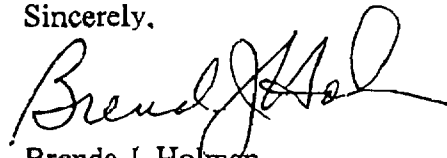
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TOPS Markets, Inc.

Within fifteen (15) working days of receipt of this letter, please notify our office in writing of the specific steps you have taken to correct the violations, including an explanation of each step being taken to prevent a recurrence of the violation(s). Your response should be directed to Sandra K. Sylvester, Compliance Officer.

A copy of this letter, except for any confidential, personal or commercial information will be placed on public display no earlier than fifteen (15) days after the date of this letter. Your response will be on public display with any confidential, personal or commercial information purged.

If you require further information, you may contact Sandra K. Sylvester at (716) 551-4461, extension 3145.

Sincerely,



Brenda J. Holman  
District Director

Enclosure

cc:

Mr. Jon Kitts, Director of Warehousing  
TOPS Distribution Center  
5873 Genessee Street  
Lancaster, New York 14086

Mr. Dave Gray, Perishable Warehouse Manager  
TOPS Distribution Center  
5873 Genessee Street  
Lancaster, New York 14086

Mr. Dave Kims, Perishable Shift Manager  
TOPS Distribution Center  
5873 Genessee Street  
Lancaster, New York 14086

Ms. Rhonda Baldwin, Manager  
Wilson Freight Services, Inc.  
250 Cooper Avenue, Suite 102  
Interstate Commerce Center  
Tonawanda, New York 14150